

**REMARKS**

The first paragraph on page 2 of the Office Action indicates that this application currently names joint inventors. This is not correct. This application was filed in the name of "Gilbert V. Levin" as the sole inventor.

The objection to the abstract has been overcome by the deletion of the bracketed number preceding the first line of the abstract.

The rejection of claim 7 under 35 USC 112, first paragraph is respectfully traversed. The Office Action indicates that it is not clear that applicant was in possession of the administration of L-tagatose or a mixture of the two isomers for a method of promoting cardiovascular health. However, the first paragraph on page 2 of the specification clearly states that an efficacious amount of tagatose, i.e., D-tagatose, L-tagatose or a mixture of the two isomers may be administered to a mammal to increase the HDL level of the mammal. Thus, applicant was clearly in possession of the invention of the use of D-tagatose, L-tagatose or a mixture of the two isomers to increase the HDL level of the mammal. No more should be required to comply with 35 USC 112, first paragraph.

The rejections of claims 1-6 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Zehner et al. U.S. Patent No. 5,356,879, are respectfully traversed. Zehner et al. teach a method for preventing the formation of advance glycosylation end-products in a mammal comprising administering to said mammal an effective amount of D-tagatose, see claim 1. In contrast, the claims herein recite "a method for promoting cardiovascular health in a mammal in need of such treatment". While the phrase "a method for promoting cardiovascular health in a mammal" is technically part of the preamble because it appears before the transition word

*Application Serial No.: 09/811,654*

“comprising”, there should be no question in this case that the phrase should be treated as a claim limitation, Rapoport v. Dement, 59 USPQ2d 1215, 1219 (US Court of Appeals for the Federal Circuit 2001). Moreover, without treating the phrase “promoting cardiovascular health in a mammal” as a claim limitation, the phrase “in need of such treatment” would not have a proper antecedent basis, Rapoport v. Dement, *supra*, at 1219.

The Office Action cites *In re Nowitzki*, for the proposition that the administration of tagatose by Zehner to reduce the occurrence of complications such as atherosclerosis due to accumulated glycosylation end products inherently anticipates applicant’s intended use for increasing HDL and would clearly promote cardiovascular health. However, *In re Nowitzki* was only cited by name and not by reference to a court reporter such as the U.S. Patent Quarterly. It may be that the Examiner intended to cite *Ex Parte Novitski*, 26 USPQ2d, 1389 (*Board of Patent Appeals and Interferences* 1993) which involved inherency. In that case, the Board found that the process performed by the reference “inherently and necessarily constitutes a method for protecting a plant from plant pathogenic nematodes”. However, a person practicing the invention disclosed by Zehner et al. would not necessarily and inherently promote cardiovascular health in the individual being treated. Further, the patient being treated for preventing the formation of advanced glycosylation end-products by the method described by Zehner et al. would not necessarily be a patient in need of treatment for promoting cardiovascular health as required by the claims of this application.

Thus, the claims of the Zehner et al. patent address the prevention of the formation of glycosylation end-products for the purpose of delaying aging. The present application addresses the promotion of cardiovascular health by increasing the high density lipid (HDL – or “good) fraction of cholesterol, thereby reducing the risk of blocked arteries. There is no identity to these two

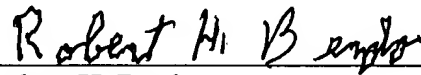
*Application Serial No.: 09/811,654*

inventions. While one might construe that any promotion of health will delay aging, this is a far less specific effect than is the prevention of glycosylation, nor does the former imply the latter. The latter cross-links protein molecules constituting muscle and brain tissue, thereby slowing down and interfering with the transmissions of signals and the response of muscles. These effects constitute aging. One skilled in the art possessing the knowledge that tagatose will reduce glycosylation would not conclude that it would also increase HDL. There is nothing in the art establishing such a relationship. Glycosylation concerns protein, HDL is a lipid, i.e., two very different types of compounds both chemically and functionally.

For the foregoing reasons, it is respectfully submitted that this application is in condition for allowance and that it should be passed to issue. Such favorable action is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In The Abstract Of The Disclosure:**

Paragraph beginning at line 1 of page 5 has been amended as follows:

~~{0006}~~ A method for promoting cardiovascular health of a mammal in need thereof, comprising administering to said mammal an efficacious amount of tagatose to raise the HDL level of said mammal.